Hydrochloride, Fluorouracil, Gentamicin Sulfate, Pentamidine Isethionate and Vancomycin Hydrochloride.

The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

94. Defendant GlaxoSmithKline, P.L.C. ("GlaxoSmithKline") is a public limited company incorporated under the laws of England and Wales, with its corporate headquarters located at 980 Great West Road, Brentford, Middlesex, United Kingdom TW8 9GS. GlaxoSmithKline was created through the December 27, 2000, merger of GlaxoWellcome, P.L.C. and SmithKline Beecham, P.L.C. GlaxoSmithKline's operational headquarters are located at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania.

95. Defendant SmithKline Beecham Corporation ("SKB"), a wholly-owned U.S. subsidiary of the former SmithKline Beecham P.L.C., is a Pennsylvania corporation with its principal place of business at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania.

96. Defendant GlaxoWellcome, Inc. ("Glaxo"), a wholly-owned subsidiary of GlaxoSmithKline, is a North Carolina corporation with its principal place of business at 5 Moore Drive, P.O. Box 13398, Research Triangle Park, North Carolina. Cerenex Pharmaceuticals ("Cerenex"), a division of Glaxo prior to the merger, was responsible for Glaxo's central nervous system drugs, including Zofran.

97. Defendants GlaxoSmithKline, SKB and Glaxo are referred to collectively as the "GSK Group."

98. The GSK Group is a diversified pharmaceutical company which controls an estimated 7 percent of the world's pharmaceutical market. In 2001, the GSK Group reported pharmaceutical sales of $24.8 billion.

99. The drugs manufactured by the GSK Group and covered by Medicare Part B include, but may not be limited to: Hycamtin® (topotecan hydrochloride), Ventolin® (albuterol) and Zofran® (ondansetron hydrochloride). Pierre Fabré Médicament licenses

another Medicare Part B drug, Navelbine® (vinorelbine tartrate), to the GSK Group. SmithKline Beecham P.L.C. manufactured and sold Kytril® (granisteron hydrochloride), another drug covered by Medicare Part B (and a competitor to Zofran®), prior to the merger. To secure regulatory approval for the merger, SmithKline Beecham P.L.C. sold Kytril®'s global rights to the Roche Group in December of 2000.

Hoffman-La Roche, Inc.

100. Defendant Hoffman-La Roche, Inc. ("Roche") is a New Jersey corporation with its principal place of business at 340 Kingsland Street, Nutley, New Jersey. Roche, is a research-based company that develops, manufacturers and markets numerous prescription and non-prescription drugs.

101. Roche is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by Roche and covered by Medicare Part B include, but may not be limited to, Cellcept® (mycophenolate mofetil), Cytovene® (ganciclovir), Demadex® (torsemide), Kytril® (granisetron HCL), Rolcatrol® (calcitriol), Rocephin® (ceftriaxone), Roferon-A® (Interferon 2-alfa), Toradol® (ketorolac tromethamine), Valium® (diazepam), Versed® (midazolam), Xeloda® (capecitabine), Zenapx® (daclizumab), Rituxan® (rituximab), Herceptin® (trastuzumab) and Xeloda® (capecitabine).

102. In addition to manufacturing and marketing drugs that are reimbursed by Medicare Plan B, Roche also manufactures and distributes other named brand drugs for which it publishes, or causes to be published, an AWP in various industry compendia.

Immunex

103. Defendant Immunex Corporation ("Immunex"), a wholly owned subsidiary of Defendant Amgen, Inc., is a Washington corporation with its principal place of business at 51 University Street, Seattle, Washington. Immunex is a company that develops products for the

treatment of cancer, asthma, rheumatoid arthritis, inflammatory diseases, infectious diseases, and cardiovascular diseases. In 1999, its total revenues were $542 million.

104. Immunex is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceutical drugs that are manufactured by Immunex and covered by Medicare Part B include, but may not be limited to Leucovorin Calcium, Enbrel® (etanercept), Novantrone® (mitoxane hydrochloride), Leukine® (sargramostim), and Thioplex®(thiotepa).

105. Defendant Immunex has been a wholly owned subsidiary of Defendant Amgen, since Immunex' acquisition in July 2002.

The Johnson & Johnson Group

106. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. In 2001, pharmaceutical sales represented 45% of J&J's worldwide sales and 19% of its operational growth. J&J is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

107. Defendant Centocor, Inc. ("Centocor") is a Pennsylvania corporation and has been a wholly owned subsidiary of Defendant J&J since its acquisition by J&J in October 1999. Centocor's principal place of business is located at 200 Great Valley Parkway, Malvern, Pennsylvania. Centocor manufactures, markets and distributes prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

108. Defendant Ortho Biotech ("Ortho") is New Jersey corporation and has been a wholly owned subsidiary of Defendant J&J since its formation by J&J in 1990. Ortho's principal place of business is located at 700 U.S. Highway 202, Raritan, New Jersey. Ortho manufactures and distributes prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

109. The drugs manufactured by J&J, Centocor, and Ortho (collectively referred to as "J&J Group") and covered by Medicare Part B include, but may not be limited to: ReoPro® (abciximab), an anti-blood clotting medication, Retavase® (reteplase), an anti blood clotting agent, Procrit® (epoetin alfa), for the treatment of anemia, Leustatin® (cladribine), for the treatment of leukemia, Orthoclone® (muromonab-CD3), used to prevent organ transplant rejection, Sporanox® (itraconazole), used in the treatment of fungal infections, and Remicade® (infliximab), an anti-inflammatory drug.

Merck & Co., Inc.

110. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation with its principal place of business located at One Merck Drive, Whitehouse Station, New Jersey. Merck is a global pharmaceutical company that develops, manufacturers and markets numerous prescription and non-prescription drugs. Sales of pharmaceutical products by Merck totaled $47.71 billion in 2001.

111. Merck is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by Merck and covered by Medicare Part B include, but may not be limited to, Aggrastat® (tirofiban hydrochloride).

112. In addition to manufacturing and marketing drugs that are reimbursed by Medicare Plan B, Merck also manufactures and distributes other named brand drugs for which it publishes, or causes to be published, an AWP in various industry compendia.

Pfizer, Inc.

113. Defendant Pfizer, Inc. ("Pfizer") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is one of the largest pharmaceutical companies in the United States, whether measured by number of prescriptions written, revenues, or market capitalization.

114. Pfizer is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide. Pharmaceuticals that are manufactured by the Pfizer Group and covered by Medicare Part B include, but may not be limited to, Cerebyx® (fosphenytoin sodium injection), Dilatin® (phenytoin), Diflucan® (fluconazole), Zithromax® (azithromycin), Trovan® (trovafloxacin mesylate), and Unasyn® (ampicillin sodium/sulbactam sodium).

115. In addition to manufacturing and marketing drugs that are reimbursed by Medicare Plan B, the Pfizer Group also manufactures and distributes other named brand drugs for which it publishes, or causes to be published, an AWP in various industry compendia.

The Pharmacia Group

116. Defendant Pharmacia Corporation ("Pharmacia") is a Delaware corporation with its principal place of business located at 100 Route 206 North Peapack, New Jersey. Pharmacia was created through the merger of Defendant Pharmacia and Upjohn, Inc. and Monsanto Company on March 31, 2000.

117. Defendant Pharmacia & Upjohn, Inc. ("P&U") is a subsidiary of Pharmacia Corp. In 1995, P&U was formed through the merger of Pharmacia AB and The Upjohn Company. P&U became a global provider of human healthcare products, animal health products, diagnostics and specialty products. In 1998, Pharmacia & Upjohn relocated its global headquarters from the United Kingdom to New Jersey. In September 1999, the company established its global headquarters on a 70-acre campus in Peapack, New Jersey. This site is now the management and pharmaceutical headquarters for Pharmacia.

118. Pharmacia is a highly diversified health care company whose business focuses on the discovery, development, manufacture and sale of a broad and diversified line of health care products and services, including pharmaceuticals, diagnostics and hospital products. Pharmacia's Prescription Pharmaceuticals business segment is involved in researching, developing, registering, manufacturing and selling prescription pharmaceutical products,

including general therapeutics, ophthalmology, and hospital products, which include oncology products and diversified therapeutics. Pharmacia reported sales of $18.1 billion for the fiscal year ended December 31, 2000. Pharmacia also reported $12.0 billion in prescription pharmaceuticals sales for the year 2001, and $10.8 billion in prescription pharmaceuticals sales for the year 2000. Prescription pharmaceuticals sales account for over 85 percent of Pharmacia's overall pharmaceutical sales. According to its Annual Report, Pharmacia's oncology drugs generated more than $1 billion in sales in 2001.

119. The drugs manufactured by Pharmacia and P&U (collectively referred to as "The Pharmacia Group") and covered by Medicare Part B include, but may not be limited to: Adriamycin PFS® (doxorubicin hydrochloride), Adrucil® (fluorouracil), Amphocin® (amphotericin), Aromasin® (bleomycin), Camptosar® (irinotecan hydrochloride), Cleocin Phosphate® (clindamycin phosphate), Neosar ® (cyclophosphamide), Cytosar-U (cytarabine), Depo-Testosterone® (testosterone cypionate), Adriamycin PFS® (doxorubicin HCL), Ellence® (epirubicin HCL), Toposar® (etoposide), Adrucil® (fluorouracil), Solu-Cortef® (hydrocortisone sodium succinate), Idamycin® (idarubicin hydrochloride), Medrol® (methylprednisolone) and Vincasar® (vincristine sulfate).

The Schering-Plough Group

120. Defendant Schering-Plough Corporation ("Schering-Plough") is a New Jersey corporation with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey.

121. Schering-Plough's primary business involves prescription products in core product categories, including allergy and respiratory, anti-infective and anticancer, cardiovasculars, dermatologicals and central nervous systems and other disorders. Schering-Plough's revenues in 2001 totaled $9.8 billion.

122. Defendant Warrick Pharmaceuticals Corporation ("Warrick"), is a Delaware corporation with its principal place of business at 12125 Moya Boulevard, Reno, Nevada.

Warrick is a wholly-owned subsidiary of Defendant Schering-Plough and has been since its formation in 1993. Warrick manufactures generic pharmaceuticals.

123. The drugs manufactured by Schering-Plough and Warrick (collectively referred to as "The Schering-Plough Group") and covered by Medicare Part B include, but may not be limited to Proventil® (albuterol sulfate), Integrelin® (eptifibatide), Intron A® (interferon alfa-2b recombinant) and Temodar® (temozolomide). The Schering-Plough Group's Albuterol sulfate sales alone totaled $154 million in 2000.

The Sicor Group

124. Defendant Sicor, Inc. ("Sicor") is a Delaware corporation with its principal place of business located at 19 Hughes, Irvine, California. Sicor was the result of the 1997 merger between Defendant Gensia, Inc. ("Gensia"), a finished dosage manufacturer, and Rakepoll Holding, a Europe-based supplier of active pharmaceutical ingredients.

125. Sicor markets itself as a vertically-integrated specialty pharmaceutical company with expertise in the development, manufacturing and marketing of injectable pharmaceutical products, primarily used worldwide by hospitals. Sicor's finished dosage products manufacturing operations account for 32% of its total revenue, and is comprised of a portfolio of products that includes oncology, anesthesiology, and critical care. Sicor's 2001 revenues totaled nearly $370 million. According to its website, Sicor operates its business through several subsidiaries.

126. Defendant Gensia Sicor Pharmaceuticals, Inc. ("Gensia Sicor"), a Delaware corporation, is a wholly-owned subsidiary of Sicor with its principal place of business located at 17 Hughes, Irvine, California. Gensia Sicor focuses on acute-care multisource products in the fields of oncology, cardiology, and anesthesiology. Gensia Sicor's injectable drug business includes more than 60 products.

127. In 1999, Gensia Sicor entered into a sales distribution agreement with Abbott Laboratories under which the two companies formed a strategic alliance for the marketing and

distribution of oncology products in the U.S. The agreement was restructured in March 2002. In 1999, Gensia Sicor also amended an earlier agreement with Baxter Pharmaceutical Products, Inc. Notably, Abbott (6%) and Baxter (34%) accounted for nearly 40% of Sicor's total product sales in 2001.

128. The drugs manufactured by Sicor, Gensia, and Gensia Sicor (collectively referred to as "The Sicor Group") and covered by Medicare Part B include, but may not be not limited to: amikacin sulfate and tobramycin sulfate.

Watson

129. Defendant Watson Pharmaceuticals, Inc. ("Watson") is a Delaware corporation with its principal place of business at 311 Bonnie Circle, Corona, California. Watson develops, manufactures and markets brand and generic pharmaceuticals. Watson is in the business of manufacturing and distributing prescription pharmaceuticals for distribution by Medicare Plan B providers nationwide.

130. The pharmaceuticals manufactured by Watson and covered by Medicare Part B include, but may not be limited to: albuterol sulfate, dexamethasone acetate, diazepam, gentamicin sulfate, iron dextran, testosterone enanthate, vancomycin hydrochloride and cytarabine.

IV. GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

131. The allegations contained herein apply generally to all defendants.

A. The AWP System

132. There are approximately 65,000 different drug products in the United States market, including different dosages of the same drug. Prescription drugs are dispensed to patients by or through different types of medical providers, including but not limited to: (a) physicians who administer the drug in an office, (b) retail pharmacies, (c) home infusion pharmacies, and (d) other medical providers.

133. Providers regularly submit claims for reimbursement, seeking payment for the drugs from Medicare, insurers and patients. During the Class Period, the Defendants were aware that the Medicare program and insurance companies (the latter are included as members of the Class) rely on published AWPs to reimburse providers for drugs. Use of the published AWPs to establish reimbursement rates for drugs is an industry-wide practice in the insurance industry.

134. There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWPs for the tens of thousands of drugs on the market, including the *Drug Topics Red Book* (the "*Red Book*"), *American Druggist First Databank Annual Director of Pharmaceuticals* and *Essential Director of Pharmaceuticals* (the "Blue Book") and Medi-Span's *Master Drug Database* (collectively referred to herein as the "Publishers"). These Publishers publish AWPs for the various dosage forms for drugs.

135. In periodically announcing the AWP for each drug, the Publishers publish the prices that are supplied to them by the Defendant Drug Manufacturers for their respective drugs. For instance, the forward to the 1999 edition of the *Red Book* states that "all pricing information is supplied and verified by the products' manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted." In addition, a June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the *Red Book*, stated that it only publishes prices that are faxed directly from the manufacturer. Thus, the Defendant Drug Manufacturers control the prices listed as the AWPs for each drug.

136. A system that bases its reimbursement rates for drugs on the published AWP is thus dependent on the honesty of the drug manufacturers. The Defendant Drug Manufacturers knew that they could directly control and fabricate the AWP for their drugs at any time by forwarding to the Publishers a new and higher AWP. The Defendant Drug Manufacturers also knew that actual transaction price data – the amounts charged to providers and others for their

drugs – was not publicly available, and they kept this information (on which AWPs should have been calculated) highly confidential and secret.

137. The AWPs for the drugs at issue here bore no relationship to the drugs' pricing in the marketplace. They were simply fabricated in furtherance of Defendants' scheme to generate the profit spread to providers, PBMs and others and to increase Defendants' profits at the expense of Plaintiffs and the Class members.

138. Plaintiffs and the members of the Class paid for the drugs based on and in reliance on the inflated AWPs reported by the Defendant Drug Manufacturers.

139. The Defendant Drug Manufacturers' pattern of fraudulent conduct in artificially inflating the AWPs for their drugs (sometimes referred to herein as the "AWP Scheme") directly caused Plaintiffs and the members of the Class to substantially overpay for those drugs.

140. As detailed below, this overpayment manifested itself in two contexts, both of which were well known and understood by the Defendant Drug Manufacturers: (i) all drugs administered under Medicare Part B and (ii) brand name drugs administered outside of the Medicare context.

B. The Defendant Drug Manufacturers' Use Of AWP Fraud To Increase Market Share For Their Drugs Covered By Medicare Part B

1. The Medicare Insurance Program

141. In 1965, Congress enacted Title XVIII of the Social Security Act ("Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care.

142. The United States Department of Health & Human Services ("HHS") is responsible for the funding, administration and supervision of the Medicare Program. The Centers for Medicare and Medicaid Services ("CMMS"), formerly known as the Health Care Financing Administration ("HCFA"), is a division of HHS and is directly responsible for the administration of the Medicare Program.

143. The Medicare Program generally does not cover the cost of prescription drugs that a Medicare beneficiary self administers (*e.g.*, by swallowing the drug in liquid or pill form). However, Medicare Part B does cover some drugs, including injectables administered directly by a doctor, certain oral anti-cancer drugs, and drugs furnished under a durable medical equipment benefit. Approximately 450 drugs are covered by Medicare Part B.

144. In determining the amount it will pay, Medicare calculates the "allowed" amount for the drug. During the period 1992 through 1997, Medicare's reimbursement for Covered Drugs was set at the lesser of the estimated acquisition cost or national average wholesale price. For generic drugs (where more than one company sells a certain drug, sometimes called multiple-source drugs), payment was based on the lower of the estimated acquisition cost or the wholesale price that was defined as the median price for all sources of the generic form of the drug. This payment methodology was set forth in 42 C.F.R. § 405.517, a regulation first published in the Federal Register on November 25, 1991 and which became effective on or about January 1, 1992.

145. The estimated acquisition cost for a drug could be determined by the Medicare program "based on surveys of the actual invoice prices paid for the drug" taking into consideration the estimated acquisition cost, including "factors such as inventory, waste and spoilage." However, historically it has been the AWP published in the *Red Book* or other compendia that has been used as a ceiling for Medicare reimbursement.

146. On January 1, 1998, 42 C.F.R. § 405.517 was amended to provide that the allowed amount would be based upon the lower of the billed charge on the Medicare claim form or 95 percent of AWP.

147. The Medicare Program has publicly announced that it would use the AWP published in pharmaceutical industry magazines as the basis for reimbursement. Specifically, Program Memorandum AB-99-63 (dated September 1999 but re-issuing PM AB-98-76 dated in December 1998), a publicly available Medicare Program bulletin, confirmed that

reimbursement for certain Medicare Part B drugs and biologicals "are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in sources such as the *Red Book*, *Blue Book*, or Medi-Span."

148. Pursuant to PM AB-99-63, the AWP for a single-source drug or biological equals the AWP of the single product. For a multi-source drug or biological, the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP.

149. Medicare Part B reimburses medical providers 80% of the allowable amount for a drug. The remaining 20% is paid by the Medicare Part B beneficiary, and is called the "co-payment" amount. All medical providers are required by law to bill the 20% co-payment and make attempts beyond merely billing to collect that amount. In addition, beneficiaries under Part B are required to pay an annual deductible amount before Part B benefits are payable.

150. Some Medicare beneficiaries are able to purchase private Medigap insurance, which covers, among other things, all or part of the 20% co-payment for Covered Drugs.

2. Congressional and Other Federal Investigations and Actions

151. The United States Department of Justice ("DOJ"), the United States General Accounting Office ("GAO"), the Office of the Inspector General at the United States Department of HHS ("OIG"), and certain Congressional subcommittees have been investigating the Defendant Drug Manufacturers and other pharmaceutical manufacturers for questionable practices regarding the industry's calculation of AWPs and for offering illegal incentives to providers.

152. In a letter dated September 28, 2000, sent from the House of Representatives Committee on Ways and Means, Subcommittee on Health to the President of the trade organization known as the Pharmaceutical Research and Manufacturers of America (most of the Defendant Drug Manufacturers are members of this association), Congressman Stark identified the improper scheme of manipulating AWPs and noted:

> This corruptive scheme is perverting financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit.

153. In his September 28 letter, Congressman Stark made the following five "shocking conclusions":

> First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.
>
> Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.
>
> Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.
>
> Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.
>
> Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

154. The DOJ and Congressional investigations are ongoing.

155. On October 13, 2001, the United States Attorney in Boston, Massachusetts announced that TAP Pharmaceutical Products Inc., a corporation that arose from a partnership between Takeda Chemical Industries, Ltd. and Abbott Laboratories, had agreed to pay $875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing practices for the drug named Lupron®. As part of the agreement:

(a) TAP agreed to plead guilty to a conspiracy to violate the Prescription Drug Marketing Act, 21 U.S.C. §§ 331(t) and 333(b), and to pay a $290 million

criminal fine, the largest criminal fine ever in a health care fraud prosecution. The plea agreement between the United States and TAP specifically stated that TAP's criminal conduct caused the Government losses of $145,000,000;

(b) TAP agreed to pay the United States Government $559,483,560 for filing false and fraudulent claims with the Medicare and Medicaid programs as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct;

(c) TAP agreed to pay the fifty states and the District of Columbia $25,516,440 for filing false and fraudulent claims with the States, as a result of TAP's drug pricing and marketing misconduct, and for TAP's failure to provide state Medicaid programs TAP's best price for Lupron®, as required by law;

(d) TAP agreed to comply with the terms of a sweeping Corporate Integrity Agreement that, among other things, significantly changes the manner in which TAP supervises its marketing and sales staff and ensures that TAP will report to the Medicare and Medicaid programs the true average sale price for drugs reimbursed by those programs;

(e) Abbott and Takeda agreed to cooperate fully with the ongoing government investigation of TAP and its former officers and employees in exchange for the United States declining prosecution of Abbott and Takeda for conduct relating to Lupron®; and

(f) An Indictment was unsealed in the District of Massachusetts against six current or former TAP employees (including an account executive, three District Managers, a National Accounts Manager and the former Vice President of Sales), and a urologist, alleging that they conspired to (i) bill Medicare for free samples of Lupron® and (ii) market Lupron® using the "spread" and the "return to practice" program.

The TAP defendants have been sued in a separate class action in connection with their fraudulent pricing and marketing practices for Lupron®.

156. At a hearing in the criminal matter, which has an extensive record, United States District Court Judge William G. Young found:

> This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

United States v. TAP Pharmaceutical Products, Inc., No. CR-01-10354-WGY (D. Mass, Dec. 6, 2001).

3. The Defendant Drug Manufacturers' Fraudulent Conduct Within the Medicare Part B Program

157. The Defendant Drug Manufacturers each perpetrated the alleged fraudulent scheme by using some and/or all of the following practices:

a. Artificially Inflating AWPs

158. Each Defendant Drug Manufacturer provided AWPs for each of its drugs to the *Red Book*, the *Blue Book*, Medi-Span and other pharmaceutical compendia.

159. During the Class Period, the Defendant Drug Manufacturers deliberately and intentionally published AWPs for Covered Drugs that did not reflect the actual pricing structure of the drugs, but was created solely to cause Plaintiffs and the Class members to overpay for the Covered Drugs. The Defendant Drug Manufacturers created and perpetuated this scheme so that the medical providers who purchased these drugs at a low cost would bill patients and their insurers at the inflated AWPs and earn a substantial profit from the "spread" between the real cost and the various AWP-related reimbursement rates.

160. The Defendant Drug Manufacturers knew and understood that Medicare and Plaintiffs and the Class members used the *Red Book* and other publications to determine the AWPs of the drugs. Because the Defendant Drug Manufacturers controlled the AWPs published in the *Red Book* and other compendia, the Defendant Drug Manufacturers knew and

understood that they could manipulate the providers' profits from Plaintiffs and the Class. The purpose of artificially inflating the providers' profits was to create an illegal kickback to the providers, funded by Plaintiffs' and the Class members' overpayments.

161. As part of their scheme, the Defendant Drug Manufacturers specifically instructed and expected the providers to charge the inflated AWPs for Covered Drugs to Medicare, Plaintiffs and the Class members.

b. Improper Use of Free Samples

162. The Defendant Drug Manufacturers, through their sales personnel and marketing representatives, also provided free samples of their drugs to providers as a means of lowering the price. The free samples were used to offset the total cost associated with the purchases of the drugs, thereby increasing the "spread." Moreover, the Defendant Drug Manufacturers specifically told providers to bill Plaintiffs and the members of the Class for the free samples, which Defendants knew was unlawful.

163. Every free sample of a drug for which a provider bills a patient or insurer effectively reduces that provider's overall cost for that drug. However, the full cost of the Covered Drug was charged to the Plaintiffs and the Class members.

164. Although the Defendant Drug Manufacturers provided free samples and marketed them as a way to lower the providers' actual cost of the Covered Drugs, they did not include the value of the free samples in calculating the AWPs for those drugs. Thus, the Defendant Drug Manufacturers effectively and improperly passed on the cost of the free samples directly to Plaintiffs and the members of the Class.

c. Other Hidden and Improper Inducements and Price Reductions

165. The Defendant Drug Manufacturers also have provided and/or arranged for many other non-public financial inducements to stimulate sales of their Covered Drugs at the expense of Plaintiffs and the members of the Class. Such inducements included volume

discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and grants. All of these incentives were designed to lower the providers' net cost of purchasing the Defendant Drug Manufacturers' Covered Drugs.

C. The Defendant Drug Manufacturers' Use Of AWP Fraud To Increase And Maintain The High Price Of Their Brand Name Drugs Outside Of The Medicare Part B Context

166. The Defendant Drug Manufacturers' AWP fraud strikes well beyond Medicare Part B, adversely impacting health plans and their participants with respect to purchases of brand name drugs.

167. Health plans typically contract with intermediaries called pharmacy benefit managers ("PBMs") so that a health plan's participants can obtain brand name drugs from pharmacies or, via mail order, directly from the PBMs. In these contracts, the brand name drugs are typically priced at AWP less a certain percentage "discount."

168. A 1996 study commissioned by HCFA reported that the price that health plans pay for brand-name, patented drugs typically fell in the range of AWP less 10 to 15%, with AWP less 13% a popular level. A 1999 survey conducted by Wyeth-Ayerst of 375 employers revealed that the average payment "discount" off AWP for brand name drugs was 13.2%. A 1999 Novartis Pharmacy Benefit Report revealed that, for the 108 HMOs that it surveyed in 1998, the average paid by the HMOs was with a 14.3% "discount" from AWP.

169. The Defendant Drug Manufacturers know that there are significant discrepancies between (i) the AWP reported by them and therefore published by the Publishers, and (ii) the prices actually paid by providers and PBMs for those same drugs. However, Defendant Drug Manufacturers continue to foster the use of the published AWP as representing the true average price from wholesalers to retailers or providers.

170. Over 70% of all Americans, or more than 200 million people, have their purchases of prescription drug products controlled through the use of a formulary program established by a PBM. The ability of a drug manufacturer to effectively market its drug

product depends on securing favorable formulary and reimbursement status from the PBMs in the market.

171. Just as the Defendant Drug Manufacturers incentivize providers under Medicare Part B to use (and submit reimbursement claims for) the drugs with the highest-inflated AWP, the Defendant Drug Manufacturers incentivize PBMs to place the brand name drugs with the highest-inflated AWPs on the PBMs' formularies by marketing the spread that the PBMs can retain the purchases of those drugs by the participants in health plans that have contracted with PBMs.

172. The Defendant Drug Manufacturers incentivize placement of their brand name drugs on formularies by marketing the spread between (i) the discounted AWP that the PBM agrees to pay retail pharmacies, and (ii) the AWP at which the health plans reimburse the PBM. Pursuant to the Defendant Drug Manufacturers' suggestion, the PBMs retain the proceeds of this "spread" without disclosure. Consequently, the PBMs are incentivized by the Defendant Drug Manufacturers to market the brand name drugs (by including those drugs on their formularies) with the highest AWPs in order to benefit from the artificial spread. Moreover, the PBMs negotiate rebates with the Defendant Drug Manufacturers at a percentage of the drug's list price or AWP. Thus, the Defendant Drug Manufacturers further inflate AWPs in order to create additional proceeds that are then passed back to the PBMs as "rebates."

D. Defendants' Concealment of the Truth

173. Each Defendant concealed its fraudulent conduct from the Plaintiffs and the Class by controlling the process by which the AWPs for Covered Drugs and brand name drugs were set. Defendants prevented Plaintiffs and the Class Members from knowing what the actual pricing structures for these drugs were, and failed to inform them of the usage of free samples and the provision of other financial incentives to providers and other intermediaries to

lower their respective costs for the drugs. Moreover, Defendants' fraudulent conduct was of such a nature as to be self-concealing.

174. Each Defendant closely guarded its pricing structures and sales figures for their Covered Drugs and brand name drugs.

175. Each Defendant also concealed its fraudulent conduct by instructing providers and others not to report the prices they paid for the Covered Drugs and brand name drugs, respectively.

176. Each Defendant also worked with and motivated provider and intermediary trade associations to halt any investigations or change in the AWP system.

177. Each Defendant's efforts to conceal its pricing structures for Covered Drugs and brand name drugs is evidence that it knew that its conduct was fraudulent.

178. Thus, each Defendant concealed that (i) its AWPs were highly-inflated (and were inflated solely to cause Plaintiffs and the Class to overpay for the Covered Drugs and brand name drugs), (ii) it was manipulating the AWPs of the Covered Drugs and brand name drugs, and (iii) the AWPs bore no relationship to the prices paid for, or the pricing structure of, the Covered Drugs and brand name drugs as they were sold to providers and others.

179. Plaintiffs and the Class, unaware of the true facts about the pricing of these drugs, have paid and continued to pay for them based upon and in reliance on the AWPs, which were the only publicly available pricing figures.

180. Plaintiffs were diligent in pursuing an investigation of the claims asserted in this Complaint. Through no fault of their own, they did not receive inquiry notice nor learn of the factual basis for their claims in this Complaint and the injuries suffered therefrom until recently.

E. Tolling of Applicable Statutes of Limitation

181. Any applicable statutes of limitations have been tolled by Defendants' knowing and active concealment and denial of the facts alleged herein. Plaintiffs and members of the Class have been kept in ignorance of vital information essential to knowledge of and the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs and members of the Class could not reasonably have discovered the fraudulent nature of the published AWPs.

182. Defendants were and continue to be under a continuing duty to disclose to Plaintiffs and the Class the fact that the published AWPs bore and continue to bear no relationship to the prices or pricing structures for Covered Drugs and brand name drugs. Because of their knowing, affirmative, and/or active concealment of the fraudulent nature of the published AWPs, Defendants are estopped from relying on any statutes of limitations.

V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

183. Due to acts of concealment by each Defendant, the following examples of the specific unlawful conduct engaged in by each particular Defendant are merely illustrative. They are not intended to be an exhaustive account of all of the unlawful activity engaged in by each Defendant.

A. Abbott

184. Abbott has engaged in an ongoing deliberate scheme to inflate AWPs. According to Pete Stark, the ranking member of the Congressional Ways and Means Committee:

> The price manipulation scheme is executed through Abbott's inflated representations of average wholesale price ("AWP") and direct price ("DP") which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is regularly referred to . . . as "the spread." The evidence . . . clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain

> drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share for certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims.

See October 31, 2000 letter from U.S. Representative Pete Stark to Miles White, Chief Executive Officer of Abbott.

185. At least one publisher, Medi-Span, has challenged the manner in which Abbott sets its AWPs. The following statement appeared in a February 9, 1996 faxed letter to Abbott from a representative of Medi-Span regarding Abbott's drug vancomycin:

> It appears that the only difference between the two products listed is the vial it comes in. If so, why the $400 difference in AWPs? This customer claims he can get Vancomycin for $6 or $7 per vial DP as opposed to the $52.94 and $19.50 the Abbott Vancomycin costs.

186. The government investigation into Abbott's AWP for vancomycin identified "prices that are routinely made available to many providers, but are far below Medicare reimbursement rates. They include 1999 prices for vancomycin, the Abbott Labs-manufactured antibiotic, which a health care provider could buy for $76.00 but for which the AWP upon which Medicare's reimbursement was based on was $261.84." *See* February 25, 2000 letter from U.S. Rep. Tom Bliley to the Honorable Nancy-Ann Min DeParle, Administrator of the Health Care Financing Administration.

187. For other doses of vancomycin, Abbott reported an AWP of $68.77 as of April 2000. DOJ adjusted it to $8.14.

188. And Abbott's AWP inflation scheme is not limited to vancomycin. One published report states: "Amikacin, used to treat an infection that HIV+ people get and manufactured by Abbott, had an AWP of $54.56. DOJ said the actual price was $6.75." *See States Mull Suit Against Drug Companies*, www.stateline.org (April 2, 2001).

189. Further, in a report published by the DHHS, the DOJ documented at least 81 instances where the published AWPs for drugs manufactured by Abbott were substantially higher than the actual prices listed by wholesalers.

190. The chart below sets forth 16 examples where Abbott deliberately inflated AWPs that it reported for Abbott's Covered Drugs. These figures compare the DOJ's determination of an accurate AWP, based upon wholesalers' price lists, with the AWP reported by Abbott in the 2001 *Red Book.*

Drug	Abbott's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Spread
Acetylcysteine	$35.87	$21.90	$13.97	64%
Acyclovir	$1047.38	$349.05	$698.33	200%
Amikacin Sulfate	$995.84	$125.00	$870.84	697%
Calcitriol (Calcijex)	$1,390.66	$1079.00	$311.66	29%
Cimetidine Hydrochloride	$214.34	$35.00	$179.34	512%
Clindamycin Phosphate	$340.52	$75.35	$265.17	352%
Dextrose	$239.97	$3.91	$236.06	6,037%
Dextrose Sodium Chloride	$304.38	$1.93	$302.45	15,671%
Diazepam	$28.50	$2.03	$26.47	1,304%
Furosemide	$74.52	$14.38	$60.14	418%
Gentamicin Sulfate	$64.42	$.51	$63.91	12,531%
Heparin Lock Flush	$38.30	$13.60	$24.70	182%
Metholprednisolone Sodium Succinate	$34.08	$2.30	$31.78	1,382%
Sodium Chloride	$670.89	$3.22	$667.67	20,735%
Tobramycin Sulfate	$150.52	$2.94	$147.58	5,020%
Vancomycin Hydrochloride	$382.14	$4.98	$377.16	7,574%

191. As set forth above, Abbott's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

B. Amgen

192. Amgen has engaged in an ongoing deliberate scheme to inflate AWPs. Amgen has reported fraudulently inflated AWPs for both epoetin alfa (sold by Amgen as Epogen®)

and filgrastim (sold by Amgen as Neupogen®). Amgen is identified in various annual *Red Book* publications as the sole manufacturer for filgrastim and as one of two sources for epoetin alfa. The other source for epoetin alfa is Defendant Johnson & Johnson.[1]

193. In September 2001, the GAO reported that epoetin alfa accounted for the second highest percentage of Medicare expenditures on drugs in 1999, accounting for 9.5% of spending for prescription drugs by Medicare in 1999 and for 3.4% of all Medicare allowed services.

194. As set forth above, Amgen's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by Plaintiffs and the Class.

C. AstraZeneca

195. AstraZeneca has engaged in an ongoing deliberate scheme to inflate AWPs. According to a September 2001 GAO report, the discount from AWP for medical providers who purchased AstraZeneca's Zoladex and billed Medicare was between 21.9% and 22.3%.

196. Internal AstraZeneca documents reveal that AstraZeneca was directly marketing the spread to physicians.

197. A memo announcing price changes for Zoladex states:

> "We have raised AWP and AWC by 7% and have increased our discount level higher at all purchasing tiers.
>
> Pricing on Zoladex 3-month is as follows:

	Discount	**AWP**	**Cost**
1-5 depots	0	1206.49	966.79
6-11 depots	11	1206.49	860.44
12-23 depots	15	1206.49	821.77

[1] Under a licensing agreement between Defendant Amgen and Defendant Johnson & Johnson, Amgen markets Epoetin Alfa for use in the treatment of dialysis patients while licensing the right to market Epoetin Alfa for all other uses to Defendant J&J.

24-47 depots	17	1206.49	802.44
48-59 depots	20	1206.49	773.43
60-71 depots	22	1206.49	754.10
72-96 depots	24	1206.49	734.76
96-191 depots	25	1206.49	725.09
192 +	30	1206.49	676.75

ZOLADEX AWP has been priced at a 5% premium above 3 times the Zoladex 1 month depot. The discount levels have been increased also."

Thus, at the same time AstraZeneca was raising the AWP for Zoladex, it was lowering the real price to providers (by giving bigger discounts), which served to widen the spread.

198. Another document sets forth the difference between the purchase price and the AWP at various volume levels. Note that even with no volume discount, a provider is still making at least a $71.00 profit per unit on Zoladex ($358.55 - 286.84 = 71.71):

NEW LOWER CASE QUANTITY DISCOUNT
ZOLADEX PRICING

UNITS	AWP	COST	DISCOUNT	LESS 2%
1-5	$358.55	$286.84	0%	$281.10
6-11	$358.55	$269.63	6%	$264.24
12-23	$358.55	$261.02	9%	$255.80
24-47	$358.55	$252.42	12%	$247.37
48-59	$358.55	$243.81	15%	$238.93
60-71	$358.55	$235.21	18%	$230.50
72+	$358.55	$229.47	20%	$224.88

199. The same document goes on to tout the practice's ability to make more profit, or return on investment, by exploiting the AWP scheme:

Thank you for your time and listening ear on Monday, April 17.
As discussed, I am offering a proposal to switch Lupron patients

> to Zoladex. Zeneca Pharmaceuticals now has new volume pricing, with a 20% maximum discount, for Zoladex. What this will offer the practice is an opportunity to save money, realize a better return on investment, achieve the same profit you currently have with our competitor and free up a substantial amount of working capital. Zoladex will also save the patient money and the system money.
>
> Based on a comparison of Zoladex and Lupron, if 480 depots are used annually Zoladex will save the practice $57,177.60 a year. Your dollar return to the practice is now slightly higher with Zoladex. This rate of return for Zoladex is now 59% compared to Lupron's 39%

200. Another AstraZeneca document even more explicitly demonstrates to providers how they can profit from the AWP scheme, in excess of $64,000 per year:

ZOLADEX

Direct Pricing	Medicare AWP	$$Return / % Return
72+ $244.88	$358.55	$133.67 59%
72x$224.88=$16,191.38	72x$358.55=$25,815.60	$9,624.24 59%
based on your use of 480 depots annually, with our 2% discount these are the comparisons		
$107,942.40	$172,104.00	$64,161.60 59%

201. AstraZeneca, through its employees and agents, also provided millions of dollars worth of free samples of its drugs to providers. The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Plaintiffs and the Class. Moreover, at least as to Zoladex®, AstraZeneca sales representatives specifically told providers that they could and should bill for the free samples.

202. A written proposal from AstraZeneca Sales representative Randy Payne dated July 17, 1995 encourages a urology practice to switch all of their patients to Zoladex and states: "AS AN ADDED INCENTIVE, ZENECA WILL PROVIDE YOU WITH 50 FREE DEPOTS(over $11,900 worth of product) FOR THE INITIAL CONVERSION TO ZOLADEX."